PATENT
PC 6794A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 4,621,638 :
ISSUED: NOVEMBER 11, 1986 :
TO: THOMAS A. SILVESTRINI :
FOR: HARD ELASTIC SUTURES :

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

APPLICATION FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C. 156

Transmitted herewith is the application of **PFIZER HOSPITAL PRODUCTS GROUP, INC.** for extension of the term of United States Patent No. 4,621,638 under 35 U.S.C. 156, together with a duplicate of the papers thereof, certified as such.

Please charge Deposit Account No. **16-1445** in the amount of $600.00. The Commissioner is hereby authorized to charge any additional fees which may be required,or credit any overpayment, to Deposit Account No. **16-1445**. Two duplicates of this paper are enclosed.

Respectfully submitted,

Dated: February 22, 1991

John L. LaPierre
Reg. No. 29,185
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(212) 573-1594

(jl)291185.jll

PATENT

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Sir:

APPLICATION FOR EXTENSION OF THE TERM OF UNITED STATES PATENT NO. 4,621,638 UNDER 35 U.S.C. 156

Your applicant, **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, a corporation organized and existing under the laws of the State of Delaware and having a place of business at **235 East 42nd Street, New York, New York,** represents that it is the owner of the entire right, title and interest in and to Letters Patent of the United States No. 4,621,638, granted to **THOMAS A. SILVESTRINI** on the 11th day of November, 1986, for HARD ELASTIC SUTURES, by virtue of an assignment recorded in the United States Patent and Trademark Office on July 15, 1985 at Reel 4430, Frame 792. Pursuant to the provisions of 35 U.S.C. 156, your applicant hereby applies for an extension of the term of said United States patent of 409 days, based upon the materials set forth herein and in the accompanying papers. In the materials which follow, paragraph numbers correspond where applicable to the paragraph numbers set forth in 37 C.F.R. 1.740(a).

(1) The approved product is a Non-Absorbable Polypropylene Surgical Suture for use in ophthalmic surgery.

(2) The suture was subject to regulatory review under Section 515 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(e)). The product was originally classified as a Class III device subject to the Section 515 review. Subsequently, the device was reclassified as a transitional device and reclassified into Class II in accordance with the

Food and Drug Administration, Notice of Reclassification, Docket Number 88P-0173, effective July 5, 1990.

(3) The Food and Drug Administration granted permission for commercial marketing or use of the suture on December 24, 1990. A copy of the Food and Drug Administration letter of approval is attached hereto as EXHIBIT A. It should here be noted that while final approval was based upon a Section 510(k) submission, prior extensive testing was governed by the provisions of Section 515 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(e)).

(4) This application is being submitted within the sixty day period permitted for its submission pursuant to 37 C.F.R. 1.720(f). The last day on which this application could be submitted is February 22, 1991.

(5) The patent for which an extension is being sought is identified as follows:

Inventor: **THOMAS A. SILVESTRINI**
Patent No.: **4,621,638**
Title: **HARD ELASTIC SUTURES**
Issued: **NOVEMBER 11, 1986**
Expires: **NOVEMBER 11, 2003**

(6) A copy of United States Patent No. 4,621,638, the patent for which an extension is being sought, is attached hereto as EXHIBIT B.

(7) No disclaimer, certificate of correction or reexamination certificate issued for United States Patent No. 4,621,638. The maintenance fee has been paid for United States Patent No. 4,621,638. Attached hereto as EXHIBIT C is a copy of receipt of Maintenance Fee Statement.

(8) United States Patent No. 4,621,638 claims the approved product. The manner in which each applicable patent claim reads on the approved product is as follows.

Claim 1 of U.S. 4,621,638 claims a surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer. The approved product is a suture having a sterile hard elastic filament of a body-compatible polymer.

Claim 2 of U.S. 4,621,638 claims a suture which is a monofilament. The approved suture is a monofilament.

Claim 3 of U.S. 4,621,638 claims a suture wherein the polymer is polypropylene. The approved suture polymer is polypropylene.

Claim 4 of U.S. 4,621,638 claims a monofilament having a diameter in the 0.020-0.039 mm range. The approved suture, which is a 9-0 suture, has a diameter in the range of from 0.030-0.039 mm.

Claim 6 of U.S. 4,621,638 claims a polypropylene suture with the Young's modulus of the filament being in a range of 0.25-5.0 g/denier. The approved suture has a Young's modulus in this range.

Claim 12 of U.S. 4,621,638 claims a needled surgical suture having at least one sterile hard elastic filament of a body-compatible polymer attached to a sterile surgical needle. The approved suture is as aforesaid in respect to claim 1 and the suture is attached to a sterile surgical needle.

Claim 13 of U.S. 4,621,638 claims a needled surgical suture wherein the polymer is polypropylene. The approved suture polymer is polypropylene.

Claims 14 and 15 of U.S. 4,621,638 claim a surgical suture package having a sterile enclosure containing a sterile needled surgical suture having at least one hard elastic filament of a body-compatible polymer and wherein the polymer is polypropylene. The approved suture is as aforesaid in respect to claim 1 and the suture is attached to a sterile surgical needle and packaged in a sterile enclosure. The approved suture is polypropylene.

Claim 16 of U.S. 4,621,638 claims a method of suturing by stitching with at least one sterile hard elastic filament made of a body-compatible polymer. The approved product is a suture for use in suturing. The suture includes a hard elastic filament made of a body-compatible polymer.

Claims 17-19 of U.S. 4,621,638 claim the method wherein the polymer used is polypropylene, the filament ranges in

diameter from 0.020-0.039 mm and the filament has a Young's modulus of 0.25-5.0 g/denier. The approved suture for use in suturing by stitching includes these characteristics as aforesaid in respect to claims 3, 4 and 6.

Claim 20 of U.S. 4,621,638 claims a method wherein the stitching is performed in corneal surgery. The approved product is a suture for use in ophthalmic surgery.

(9) The relevant dates and information pursuant to 35 U.S.C. 156(g) in order to permit the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows.

(a) The IDE application was conditionally approved February 5, 1988. The IDE number assigned was G880005. Final IDE approval was given March 11, 1988.

Human clinical investigation involving the device began March 1, 1988.

(b) The completed final product report was submitted August 21, 1990. A Section 510(k) application was filed on August 21, 1990 and the application was give identification number K903643. The Section 510(k) was filed instead of a Section 515 since the device was reclassified as a transitional device and reclassified into Class II as aforestated in Paragraph (2) herein.

(c) On November 27, 1990, the Food and Drug Administration declared that the application was completed.

(10) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is attached hereto as EXHIBIT D.

(11) Applicant is of the opinion that United States Patent No. 4,621,638 is eligible for an extension under 35 U.S.C. 156 and the length of extension claimed is 409 days. The length of extension of the term of U.S. Patent No. 4,621,638 of 409 days claimed by applicant was determined according to the provisions of 35 U.S.C. 156(c) and 156(g). The period of extension is calculated according to the formula

Period = ½ (Testing Phase) + Approval Phase

wherein the Testing Phase herein equals the number of days between the human clinical evaluation and submission of the final report (March 1, 1988 through August 21, 1990) or 903 days and the Approval Phase equals the number of days from the submission of the completed report to the date of product approval (August 21, 1990 through December 24, 1990) or 125 days. Thus,

Period = ½ (903) + 125
= 452 + 125
= 577 days

However, the exception of 35 U.S.C. 156(c)(3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (December 24, 1990) when added to the period of extension calculated above (577 days) cannot exceed fourteen (14) years. The period of extension is thus limited to December 24, 2004 by operation of 35 U.S.C. 156(c)(3). Since the patent term of seventeen (17) years would expire November 11, 2003, the period of extension is the number of days to extend the term of the patent to December 24, 2004 or four hundred and nine (409) days.

(12) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the four hundred and nine day extension being sought to the term of United States Patent No. 4,621,638.

application for extension is to be charged to Deposit Account No. 16-1445, as authorized in the enclosed transmittal letter.

(14) Please address all inquires and correspondence relating to this application for patent term extension to:

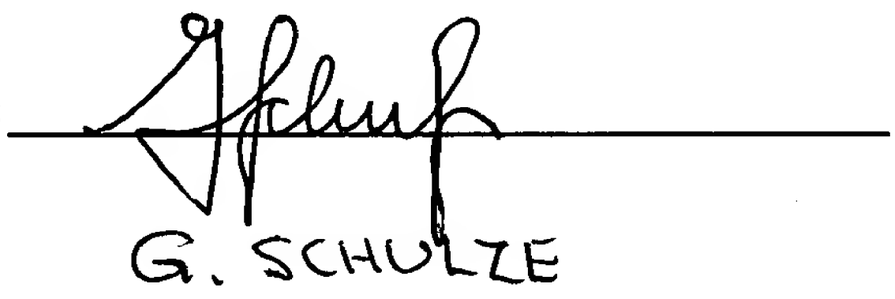
John L. LaPierre
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(212) 573-1594

(15) A duplicate of these application papers, certified as such, is enclosed herewith.

(16) A declaration pursuant to 37 C.F.R. 1.740(a)(17) and 1.740(b) is enclosed herewith.

Respectfully submitted,

PFIZER HOSPITAL PRODUCTS GROUP, INC.

Dated: February 22, 1991 by: 
G. SCHULZE

Pfizer Inc.
Patent Department, 20th Floor
235 E. 42nd Street
New York, NY 10017-5755
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PATENT

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ISSUED: NOVEMBER 11, 1986 :
TO: THOMAS A. SILVESTRINI :
FOR: HARD ELASTIC SUTURES :

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

DECLARATION ACCOMPANYING APPLICATION OF PFIZER HOSPITAL PRODUCTS GROUP, INC. FOR EXTENSION OF THE TERM OF U.S. PATENT NO. 4,621,638 UNDER 35 U.S.C. 156

I, Gerald H. Schulze, declare as follows:

THAT I am a Sr. Vice President of **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, and that I am authorized to obligate said **PFIZER HOSPITAL PRODUCTS GROUP, INC.**;

THAT I have reviewed and I understand the contents of the application of **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, dated February 22, 1991, which is being submitted herewith for extension of the term of United States Patent No. 4,621,638 under 35 U.S.C. 156;

THAT I believe that United States Patent No. 4,621,638 is subject to extension pursuant to 35 U.S.C. 156 and 37 C.F.R. 1.710;

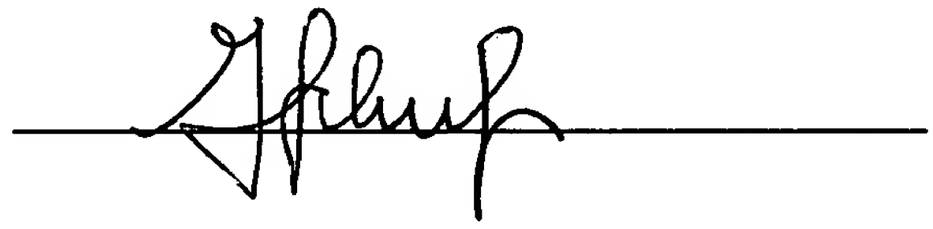
THAT I believe that the extension of term of United States Patent No. 4,621,638 of 409 days which is being claimed by **PFIZER HOSPITAL PRODUCTS GROUP, INC.** is justified under 35 U.S.C. 156 and the applicable regulations; and

THAT I believe that the patent for which extension is being sought meets the conditions for extension of the term of a patent as set forth in 35 U.S.C. 156 and 37 C.F.R. 1.720.

I declare further that all statements made herein of my own knowledge are true and that all statements made on

information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application being submitted herewith or any extension of patent term granted hereon.

Signed this 22nd day of February, 1991 at New York, New York.



(jl)291187.jll

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

EXHIBIT A

DEC 24 1990

Mr. Harry Savard
Manager, Regulatory Affairs
Deknatel Division
Pfizer Hospital Products Group, Inc.
600 Airport Road
P.O. Box 2980
Fall River, Massachusetts 02722-2980

Re: K903643
Dekantel® Microflex™ Ophthalmic
Dyed Polypropylene Suture
Dated: October 30, 1990
Received: October 31, 1990

Dear Mr. Savard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification will be announced in a future Federal Register notice. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Deknatel® Microfelx™ Ophthalmic Polypropylene Nonabsorbable Surgical Suture is indicated for use in ophthalmic surgery only.

2. This device may not be manufactured from any material other than a long chain polyolefin polymer known as polypropylene. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacture of the Polypropylene surgical suture. Any deviation of the source material or processing as described in this 510(k) notification must be submitted to the Food and Drug Administration (FDA) in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substancial equivalence of your device to a reclassified transitional device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for David L. West, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

United States Patent [19]

Silvestrini

[11] **Patent Number: 4,621,638**

[45] **Date of Patent: Nov. 11, 1986**

[54] **HARD ELASTIC SUTURES**

[75] Inventor: **Thomas A. Silvestrini**, East Lyme, Conn.

[73] Assignee: **Pfizer Hospital Products Group, Inc.**, New York, N.Y.

[21] Appl. No.: **754,716**

[22] Filed: **Jul. 15, 1985**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 635,790, Jul. 30, 1984, abandoned.

[51] **Int. Cl.**[4] **A61B 17/00**

[52] **U.S. Cl.** ..... **128/335.5**; 264/176.F 264/178 F

[58] **Field of Search** ..... 128/335.5; 264/176 F, 264/178 F

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,359,983	12/1967	Northey	128/335.5
3,454,011	7/1969	Wagner	128/335.5
3,565,077	2/1971	Glick	128/335.5
3,630,205	12/1971	Listner	128/335.5

Primary Examiner—Jacqueline V. Howard
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Gezina Holtrust

[57] **ABSTRACT**

A surgical suture made of a polymer filament having the "hard" elastic properties of reversible elasticity and retention of diameter on stretching.

20 Claims, 3 Drawing Figures

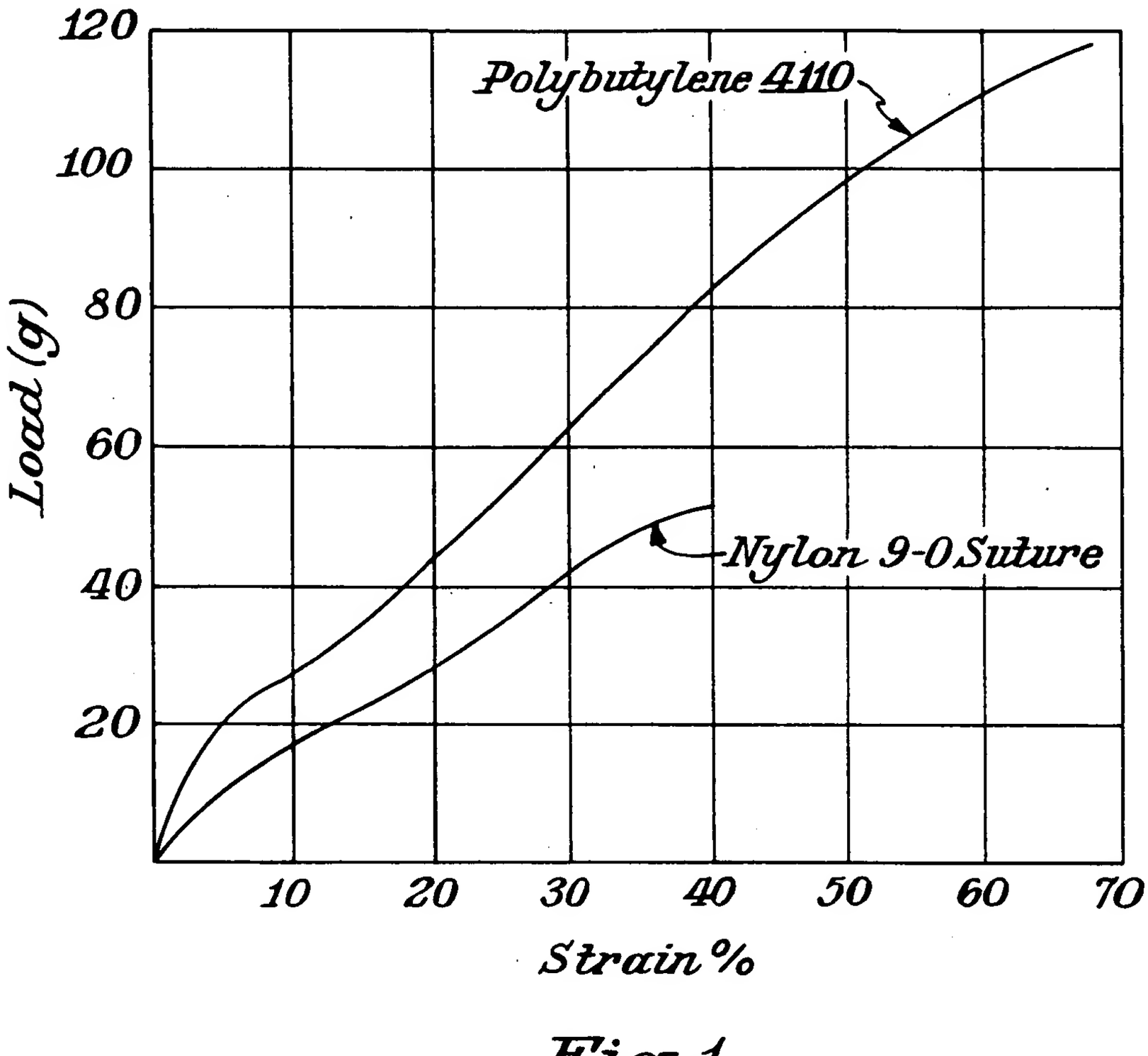

120
100
80
60
40
20
Load (g)
Polybutylene 4110
Nylon 9-0 Suture
10
20
30
40
50
60
70
Strain %

Fig. 1.

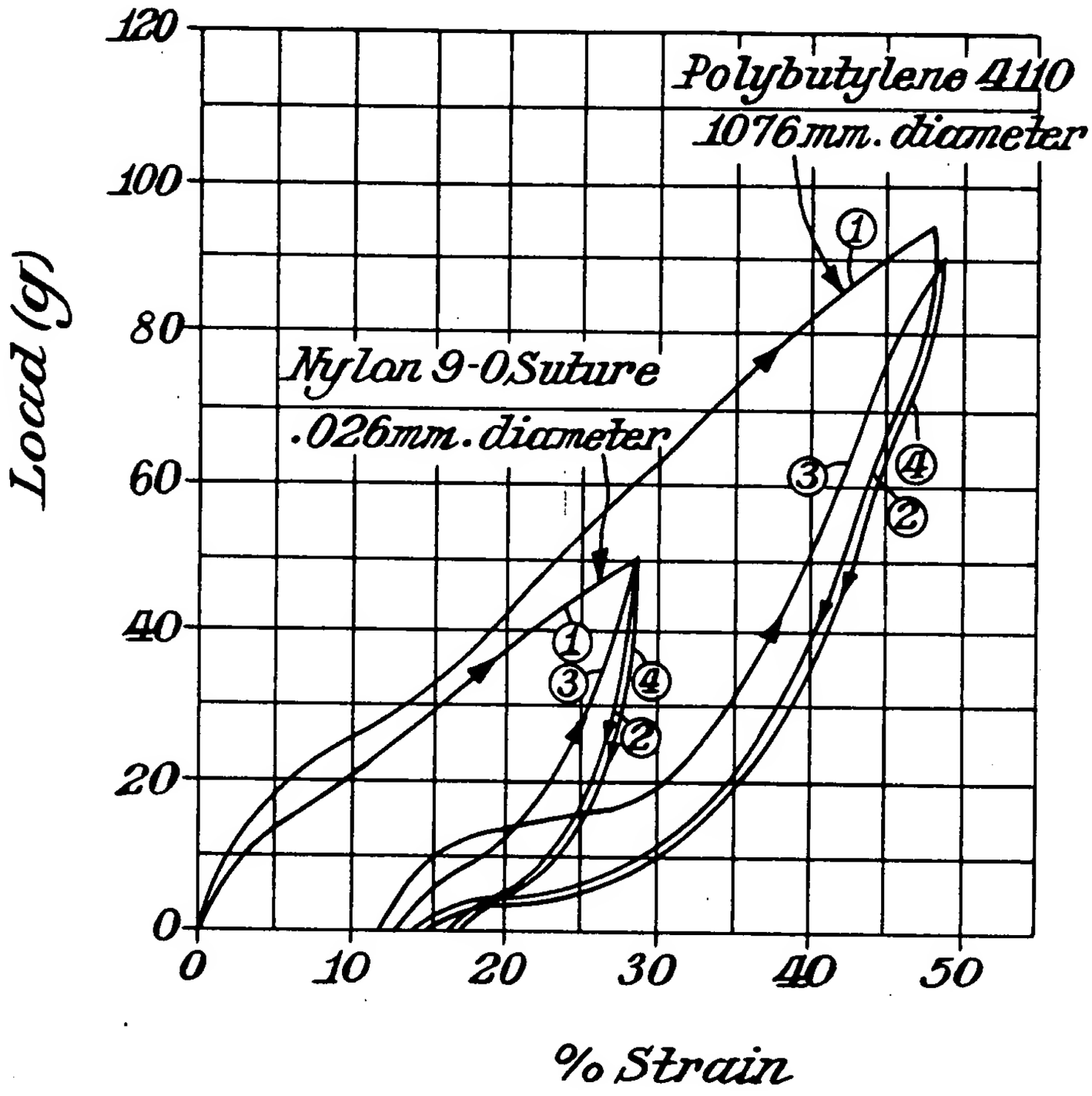

120
100
80
60
40
20
0
Load (g)
0
10
20
30
40
50
% Strain
Polybutylene 4110
1076mm. diameter
Nylon 9-0 Suture
.026mm. diameter
1
2
3
4

Fig. 2.

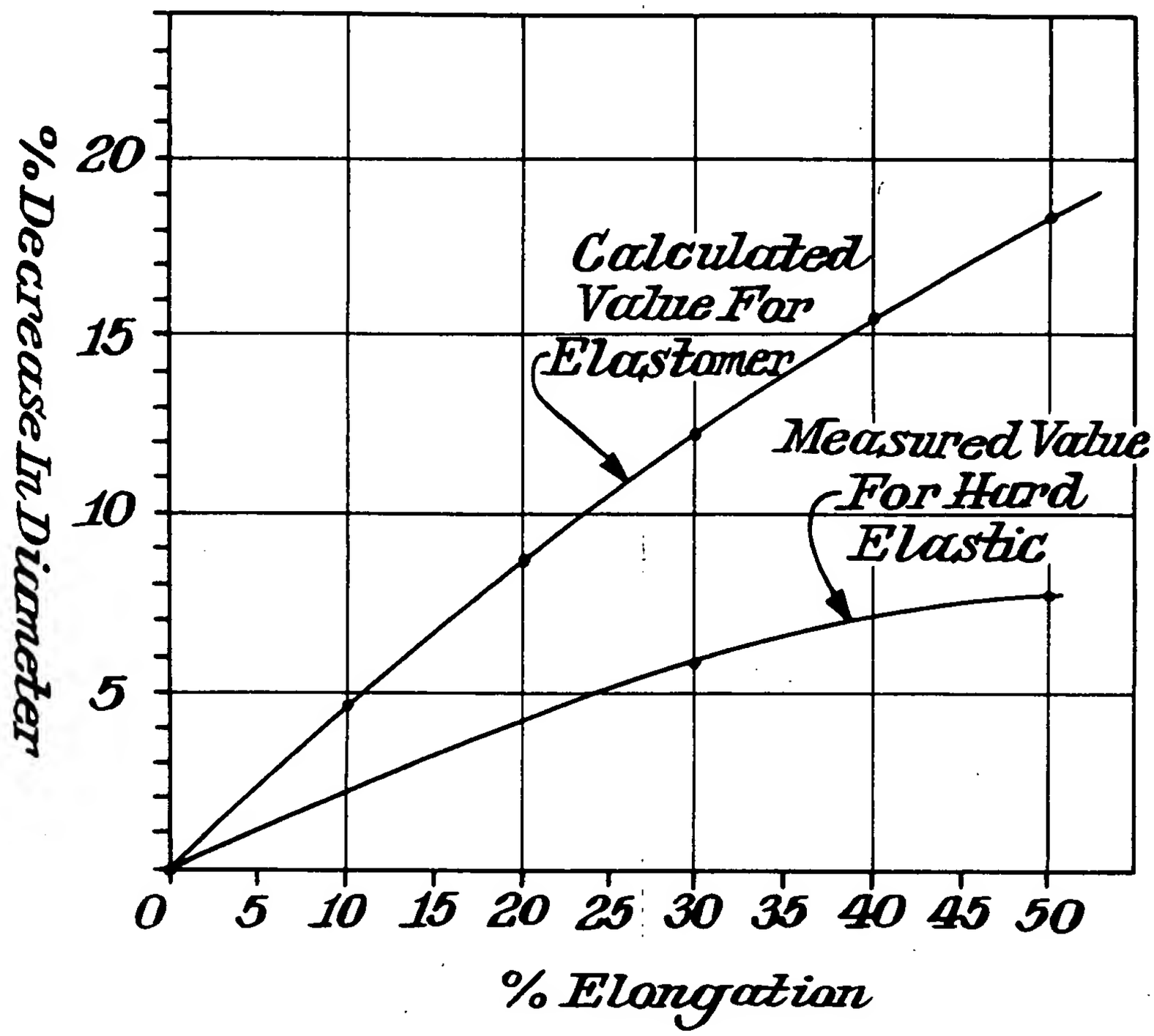

% Decrease In Diameter
20
15
10
5
0
5
10
15
20
25
30
35
40
45
50
% Elongation
Calculated Value For Elastomer
Measured Value For Hard Elastic

Fig. 3.

HARD ELASTIC SUTURES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 635,790, filed July 30, 1984, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to the field of surgical sutures, more particularly to the field of fine sutures for corneal surgery.

Opthalmic sutures are necessarily of fine gauge, and so must be made of strong filaments. However, if the suture is too fine, even though strong, the suture can cut through and damage the corneal tissue. If too large, the suture will not allow burying the suture knot in the sclera and results in irritation and discomfort. Conventional ophthalmic sutures are generally made of nylon filaments. These materials produce sutures that perform reasonably well, but still have deficiencies. In particular, they are not elastic enough to expand and contract adequately with tissue swelling due to edema. This can result in damage and poor wound healing. Therefore, it would be advantageous to have an elastic opthalmic suture. However, most elastic filaments shrink in diameter as they elongate. This makes them unsuitable for use as opthalmic sutures because, as the wound swells and tension in the suture increases, the suture diameter decreases. This reduced diameter coupled with the increased tension make it more likely that the suture will cut through and damage the delicate tissue.

Thus, the ideal suture for corneal tissue would be of high strength to allow use of fine size, reversibly elastic to accommodate edema, and capable of substantially maintaining its initial diameter when elongated to minimize cutting through tissue.

U.S. Pat. No. 3,630,205 discloses flexible polypropylene sutures. However, the polypropylene used is not a "hard" elastic material as defined hereafter.

SUMMARY OF THE INVENTION

According to the invention, a suture is made of hard elastic filaments of a body-compatible polymer.

The term "hard elastic" is used by R. G. Quinn et al., J. Macromol. Sci. Phys., B5(4), 721–738 (Dec., 1971) with reference to fibers prepared from semicrystalline polymers having long range mechanical elasticity, i.e. a high degree of length recovery from large extensions, specifically at least about 90% recovery on 30% extension, a marked reduction in apparent density on stretching, and generation of very large amounts of accessible volume and surface area on stretching. The large, mainly reversible reduction in apparent density on stretching sharply distinguishes the hard elastic filament from elastic filaments. This reduction in density results in little or no decrease in filament diameter on stretching.

In accordance with the invention, a hard elastic filament is one which (1) shows substantially less decrease in filament diameter on stretching when compared to conventional elastomeric filament, (2) is at least about 90% reversibly elastic on elongation of up to 30% subsequent to one elongation and relaxation cycle, and (3) exhibits characteristic elasticity in which the slope of the stress strain curve of the filament changes without plastic yield deformation.

As to (2) above, the 90% reversible elasticity on 30% elongation is found in elongation and relaxation cycles subsequent to the first elongation and relaxation cycle.

The hard elastic filament according to the invention is made from a polymer having a special crystalline morphology which is a result of specific high stress spinning conditions described in the art cited hereafter.

Polymers capable of forming hard elastic filaments under high stress spinning conditions are polyolefins such as isotactic polybutylene (also known as poly(butene-1)), isotatic polypropylene(PP) and polyethylene(PE), and mixtures of isotactic and non-isotactic polyolefins.

Isotactic copolymers of olefins such as butene-1/ethylene copolymers and blends of isotactic homo- and copolymers of olefins such as PP/PE blends are suitable as well. Examples of other suitable polymers are polyoxymethylene, polyisobutylene oxide, polyester and nylon. All of the above polymers are suitable for use as nonabsorbable sutures.

Other suitable polymers are polycaprolactone, polycaprolactam, polyhydroxybutyric acid(PHB), polyglycolic acid(PGA) and polylactic acid(PLA), and blends thereof such as blends of PGA and PLA, and PHB and PGA. These polymers are slowly absorbable in the body and may therefore be made into absorbable sutures.

The manufacture of hard elastic filaments is described in the art, for instance in U.S. Pat. Nos. 4,006,208 (polyisobutylene oxide), 3,840,510 (butene-1 polymers), 3,686,385 (poly(butene-1)), 3,549,743 (PP), 3,513,110 (polyester and polycarbonamide), 3,432,590 (PP), 3,323,190 (PP), 3,330,897 (polyolefines) and 3,256,258 (PP), the disclosures of which patents are herewith incorporated by reference.

Fine gauge sutures can be made of hard elastic filaments in either monofilament or multifilament form. While fine gauge hard elastic monofilament sutures are especially suitable for opthalmic use, larger diameter monofilament and multifilament sutures are useful in general surgery.

It is the purpose of this invention to provide a suture which is reversibly elastic to stretch on wound swelling, but does not significantly decrease in diameter during that elongation. It is another purpose to provide such a suture as a fine gauge monofilament suitable for opthalmic use.

DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 presents stress-strain curves of a nylon 9-0 suture (0.036 mm. diameter) and a polybutylene filament according to the invention.

FIG. 2 presents hysteresis curves of the nylon suture and the polybutylene filament.

FIG. 3 presents curves comparing the % decrease in diameter vs. % elongation of a conventional elastomeric filament with a hard elastic filament of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Continuous filaments with hard elastic properties can be made from a number of highly crystalline polymers that are also suitable for use as sutures in the human body, as described above. Filaments made of polybutyl-

ene and PP/PE blends are advantageous since hard elastic properties are reliably obtained on proper processing of these polymers. Isotactic PP is advantageously used because of combination of high strength and good eye-compatibility. A suitable grade of crystalline isotactic PP is sold by Hercules Inc. under the trademark "Profax". Shell Polybutylene 4110, 0400, 0300, 0200, 8640, 8240 and 8010 are suitable butylene and butylene-ethylene polymers available from Shell Chemical Company. Exxon polypropylene (DMF #492) is a suitable mixture of isotactic and non-isotactic polypropylene available from the Exxon Corporation.

A conventional elastomeric filament has a constant density and volume during stretching so that the diameter of the filament must decrease during stretching. Such decrease can be accurately calculated. The results of such calculations are set out in FIG. 3 and below as follows:

% Elongation	% Decrease in Diameter
0	0
10	4.7
20	8.7
30	12.3
40	15.5
50	18.4

The measured decrease in diameter for a hard elastic polypropylene filament of size 9-0 (0.036 mm) of the invention is set out in FIG. 3. As shown in FIG. 3, the measured decrease in diameter of the hard elastic filament is substantially less than the calculated diameter decrease of the conventional elastomeric filament. Generally, the % diameter decrease of a hard-elastic filament of the invention ranges from 0 to 10% on 50% stretching, and from 0 to about 8% in the case of the hard elastic filament of FIG. 3.

According to one embodiment of the invention, the hard elastic filament shows little or no decrease in diameter on stretching, e.g. about 3 to 4% diameter decrease on stretching to 25%, 30% or 50% of the original length.

According to a preferred embodiment of the invention, on 100% extension the filament has at least about 80% instantaneous recovery and 10% remaining recovery within a few minutes.

Generally, a monofilament suture having a Young's modulus of about 0.25 g/d to about 5.0 g/d is suitable for use in the invention, although this range is not critical to the invention. When softer hard elastic filaments are desired, the filament may be subjected to a final heat treatment step while the filament is in a stretched condition. For example, H. D. Noether et al., Textile Res. J., 46, 467–478 (1976) report production of hard elastic filaments with much reduced Young's modulus by heat treatment at 130° C. and 100% extension for 30 minutes. Materials of high elasticity in the 1–10 g/d modulus range and having tenacities between 1 and 4 g/d are formed.

The invention is not limited to hard elastic filaments made by any particular method. In general, hard elastic filaments may be produced from suitably crystalline polymers by spinning under high stress conditions as known to those skilled in the art. The high stress spinning conditions, particularly the melt temperature and draw ratio, depend on the particular polymer material being used. For instance, polybutene-1 generally requires spinning at melt temperatures of about 190° to 300° C. and at draw ratios of about 10 to about 5,000, preferably 100 to 400. Polybutylene oxide requires a melt temperature of from about 175° C. up to the decomposition temperature of polybutylene oxide and a draw ratio of about 50 to 1000, preferably 300 to 500. Polypropylene requires generally a melt temperature of about 160° to 260° C. and draw ratios of about 60 to 300. Temperatures of above about 60° C. and above about 100° C. are used for polyamides and polyesters, respectively, with draw ratios of about 200 to 4,000.

After suitable hard elastic filaments have been produced, they must be converted into sutures. If the suture is not to be a monofilament, a plurality of filaments may be combined, as by braiding, into a multifilament braid. The monofilament or multifilament strand is cut into desired lengths and sterilized. Needles may be attached. The sutures, with or without needles, are packaged in sterile enclosures to maintain sterility until time of use. Alternatively, sterilization may take place after packaging. Methods for carrying out these conversion steps are well known in the art, and the invention is not limited to any particular combination of them.

Monofilament hard elastic sutures in 9-0 (0.030–0.39 mm in diameter) and 10-0 (0.020–0.029 mm in diameter) size are especially useful for ophthalmic surgery. However, both mono- and multifilament hard elastic sutures can be made in a wide range of sizes suitable for many surgical procedures. The unusual elastic properties of the sutures of the invention will be beneficial to surgery requiring difficult anastomosis such as bowel and blood vessel anastomosis, and microsurgery to reconnect nerves. The sutures of the invention are also uniquely suitable in plastic and reconstructive surgery generally using a size range of about 4-0 (0.15–0.199 mm in diameter) to 7-0 (0.05–0.069 mm in diameter), and preferably 5-0(0.10–0.149 mm in diameter). Also, sutures according to this invention can be made of any body-compatible polymer that can be sterilized, has the required strength and can exhibit the property of hard elasticity. The sutures of the invention can be dyed with dyes conventionally utilized in corneal surgery such as copper phthalocyanine.

The following example illustrates the invention.

EXAMPLE

Polybutylene (Shell Polybutylene 4110) was melt-spun into a multifilament yarn at a spin draw ration of 126. Table 1 sets out the physical properties of the polybutylene (PB) used. Individual filaments in the yarn measured 0.076 mm. in diameter. A hard elastic PB filament was formed having a stress-strain curve and a cyclic load-strain hysteresis curve characteristic of hard elastic filaments as shown in FIGS. 1 and 2.

The change in the slope of the curve for the PB filament at about 6% strain in FIG. 1 does not represent a yield point where deformation is irreversible. The PB filament broke at about 68% strain and showed good recovery up to 50% strain.

The curve for the nylon suture in FIG. 1 has two yield points at about 4% and about 35% strain. The nylon suture thus has two yield points before 50% strain whereas the PB filament has none. The nylon suture broke at 50% strain and showed no recovery after 35% strain.

The initial elastic recovery ratio of the PB filament after one elongation (1) to 50% of the original length and relaxation (2) was about 75%. FIG. 2 also presents

the hysteresis curve on second elongation (3) and relaxation (4). Recovery ratios increased to about 96% after elimination of residual set in the first elongation relaxation cycle. The final reversible elongation was at least 30% with 96% recovery.

FIG. 2 shows the hysteresis curves of the nylon suture after one elongation (1) relaxation (2) cycle and a second elongation (3) relaxation (4) cycle. The nylon suture has 60% elastic recovery after the first cycle to 30% strain, and 78% elastic recovery on subsequent cycles. The final reversible elongation was only 15% with 78% recovery.

TABLE 1

	ASTM Test	English		Metric	
	Method	Unit	Value	Unit	Value
General properties					
Melt index	D 1238	—	—	g/10 min	0.4
Density	D 1505	lb/ft^3	57.1	g/cm^3	0.915
Mechanical properties					
Tensile strength at yield	D 638	psi	2400	kg/cm^2	170
Tensile strength at break	D 638	psi	4800	kg/cm^2	340
Elongation at break	D 638	%	280	%	280
Modulus of elasticity	D 638	psi	38,000	kg/cm^2	2700
Thermal Properties					
Melting point range	DTA	°F.	225–259	°C.	124–126
Softening point vicat	D 1525	°F.	235	°C.	113

I claim:

1. A surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer.

2. A surgical suture as in claim 1 wherein the suture is a monofilament.

3. A surgical suture as in claim 2 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

4. A surgical suture as in claim 3 wherein the monofilament is 0.020–0.039 mm in diameter.

5. A surgical suture as in claim 2 wherein the monofilament is 0.05–0.199 mm in diameter.

6. A surgical suture as in claim 2 wherein the polymer is polypropylene or poly(butene-1) and the Young's modulus of the filament is 0.25–5.0 g/denier.

7. A surgical suture as in claim 1 wherein the suture is a multifilament suture.

8. A surgical suture as in claim 7 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

9. A surgical suture as in claim 8 wherein the multifilament suture is a braided suture.

10. A surgical suture as in claim 1 wherein the polymer is a body-absorbable polymer.

11. A surgical suture as in claim 10 wherein the polymer is selcted from the group consisting of polyhydroxybutyric acid, polyglycolic acid and polylactic acid.

12. A needled surgical suture comprising at least one sterile hard elastic filament of a body-compatible polymer attached to a sterile surgical needle.

13. A needled surgical suture as in claim 12 wherein the polymer is polypropylene or poly(butene-1).

14. A surgical suture package comprising a sterile enclosure containing a sterile needled surgical suture, the suture comprising at least one hard elastic filament of a body-compatible polymer.

15. A surgical suture package as in claim 14 wherein the polymer is polypropylene or poly(butene-1).

16. A method of suturing by stitching with at least one sterile hard elastic filament made of a body-compatible polymer.

17. A method as in claim 16 wherein the polymer is selected from the group consisting of polypropylene, poly(butene-1), ethylene-butylene copolymer, nylon and polyester.

18. A method as in claim 17 wherein the polymer is polypropylene and the filament is 0.020–0.039 mm. in diameter.

19. A method as in claim 17 wherein the filament has a Young's modlus of 0.25–5.0 g/denier.

20. A method as in claim 16 wherein said stitching is performed in corneal surgery.

* * * * *

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D. C. 20231

PAYOR NUMBER
000127

EXHIBIT C

PFIZER INC.
APR 05 1990
PATENT DEPT

BERNICE CUMMINGS
PFIZER INC.
PATENT DEPARTMENT - 20TH FLOOR
235 EAST 42ND STREET
NEW YORK, NY 10017

DATE MAILED
04/02/90

097260

MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

TM IBR	PATENT NUMBER	FEE CDE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	4,620,533	173	490	----	06/776,259	11/04/86	09/16/85	04	NO	PAID
2	4,621,630	173	490	----	06/485,541	11/11/86	04/15/83	04	NO	PAID
3	4,621,638	173	490	----	06/754,716	11/11/86	07/15/85	04	NO	PAID
4	4,624,256	173	490	----	06/774,636	11/25/86	09/11/85	04	NO	PAID
5	4,631,082	173	490	----	06/703,352	12/23/86	02/20/85	04	NO	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (*) will appear in the "status" column. Where an asterisk (*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITM NBR	ATTY DKT NUMBER
1	PC(HD) 6926
2	DPCH06674
3	PC 6794A
4	PC 6973

DIRECT THE RESPONSE TOGETHER WITH PART B OF THIS NOTICE, AND ANY QUESTIONS ABOUT THIS NOTICE TO: COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231

PTOL-#39 (REV. 1-86)

PART A

EXHIBIT D

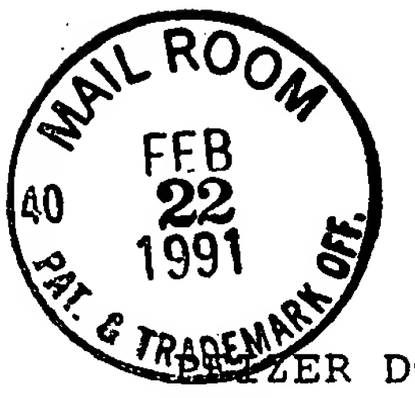
CHRONOLOGY OF NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE CLINICAL INVESTIGATION

December 23, 1987	<u>FDA Telephone Contact Report:</u> Feasibility Study Request
January 11, 1988	Submission of Clinical Feasibility Studies
January 12, 1988	Submission Received at FDA and Assigned IDE NO. G880005
February 5, 1988	Conditional Approval of IDE Application Request for Additional Information
February 25, 1988	Submission of IDE Supplement with Additional Information
March 3, 1988	Human Clinical Studies Began
March 11, 1988	Approval of IDE Application
August 5, 1988	6-Month Report-Investigator List
September 29, 1988	<u>FDA Meeting Report</u>: Suggested that Feasibility IDE Study be Supplemented to Increase Patient Numbers
October 19, 1988	<u>FDA Meeting Report</u>: Summarized Ophthalmic Study and USP vs. Elastic Suture Specs
January 9, 1989	IDE Supplement for Investigational Plan Changes
February 6, 1989	IDE Supplement Approval
February 28, 1989	Yearly Progress Report
August 31, 1989	6-Month Report-Investigator List
May 1, 1990	Human Clinical Studies Completed
May 2, 1990	Annual Progress Report

EXHIBIT D - (Continued)

June 7, 1990	FDA Acknowledgement of May 2, 1990 Report
August 21, 1990	Final Report IDE G880005
September 10, 1990	Final Report - Request for Additional Information
September 27, 1990	Response to Request for Additional Information
September 28, 1990	FDA Requested Additional Information
October 16, 1990	FDA Telephone Questionnaire for Additional Information
October 26, 1990	FDA Documented Telephone Questionnaire Dated 10/16/90
November 27, 1990	FDA Acknowledged Completion of IDE Final Report and Clinical Study

(jl)291188.jll



EXPRESS MAIL CERTIFICATE

PFIZER DOCKET: PC 6794 A

TITLE: HARD ELASTIC SUTURES U.S. PATENT 4,621,638
APPLICATION FOR EXTENSION OF TERM UNDER 35USC 156

APPLICANT: PFIZER HOSPITAL PRODUCTS GROUP, INC.

"Express Mail" mailing label number B67422166

Date of Deposit FEBRUARY 22, 1991

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

JOHN L. LAPIERRE
(Typed or printed name of person mailing paper or fee)

John L. LaPierre
(Signature of person mailing paper or fee)

PFIZER INC.
PATENT DEPT.
235 East 42nd Street
NEW YORK, N.Y. 10017-5755

1/90
M.16
(1/1)

PATENT
PC 6794A

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 4,621,638:
ISSUED: NOVEMBER 11, 1986 :
TO: THOMAS A. SILVESTRINI :
FOR: HARD ELASTIC SUTURES :

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

CERTIFICATION

I hereby certify that attached hereto is a duplicate copy of the application papers of **PFIZER HOSPITAL PRODUCTS GROUP, INC.**, dated February 22, 1991, for extension of the term of United States Patent No. 4,621,638 under 35 U.S.C. 156.

Respectfully submitted,

Dated: February 22, 1991

John L. LaPierre
Reg. No. 29,185

Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(212) 573-1594

(jl)291186/JLL

PATENT

PC6794A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE: U.S. PATENT NO. 4,621,638	:	APPLICATION FOR
ISSUED: NOVEMBER 11, 1986	:	EXTENSION OF THE TERM
TO: THOMAS A. SILVESTRINI	:	OF U.S. PATENT NO.
FOR: HARD ELASTIC SUTURES	:	4,621,638 UNDER
		35 U.S.C. 156

Hon. Commissioner of Patents and Trademarks
Box Patent Extension
Washington, D.C. 20231

Sir:

AMENDMENT

An application for extension of the term of the above-identified patent was filed February 22, 1991. Upon rereading the application papers, it was noted that clerical errors existed in the documents filed. Accordingly, for assisting the Patent Office in its processing of the application, these noted inaccurances are herein identified as follows.

On application page 6, item (11), line 11 should have read:

between the beginning of the human clinical evaluation period and submission of the

The first line of application page 7 should read:

(13) The prescribed fee for receiving and acting on this

Exhibit D, the entry date identifying the beginning of human clinical studies should have read:

March 1, 1988

Exhibit D, the entry opposite September 28, 1990 should have read:

FDA Received Requested Additional Information

Please enter this clarifying amendment into the application file. A duplicate of this paper is enclosed herewith.

We apologize for any inconvenience our errors might have caused. We await the Patent Office determination of eligibility on our application for extension of the patent term under 35 U.S.C 156.

Respectfully submitted,

Dated: February 25, 1991

John L. LaPierre
Reg. No. 29,185

Pfizer Inc.
Patent Dept., 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(212) 573-1594

(jl)291193.jll

EXPRESS MAIL CERTIFICATE

PFIZER DOCKET: PC 6794 A

TITLE: HARD ELASTIC SUTURES U.S. PATENT 4,621,638
APPLICATION FOR EXTENSION OF TERM UNDER 35USC156

APPLICANT: PFIZER HOSPITAL PRODUCTS GROUP, INC.

"Express Mail" mailing label number B 268 184 19 Y

Date of Deposit FEBRUARY 25, 1991

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

JOHN L. LAPIERRE
(Typed or printed name of person mailing paper or fee)

John L. LaPierre
(Signature of person mailing paper or fee)

PFIZER INC.
PATENT DEPT.
235 East 42nd Street
NEW YORK, N.Y. 10017-5755